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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,325	12/23/2004	Hiroshi Tanaka	62639(46342)	9306

21874 7590 11/21/2006

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EXAMINER	
HUFF, SHEELA JITENDRA	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/519,325	TANAKA ET AL.	
	Examiner	Art Unit	
	Sheela J. Huff	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *EXHIBITS A and B*.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a compound which inhibits the activity of a protein having a seqeunce the same as or similar to SEQ Id No. 1. In view of this WO 00/70945 and WO 02/062975 discloses sequences which read on SEQ ID No. 1 of sequences similar to SEQ Id NO. 1 and the screening for compounds that modulate (ie inhibit) the activity of their sequences and untimlate compounds that do possess said activity and therefore the references read on the claim. WO 00/70945 teaches sequences in figures 2 and 4 which are similar to SEQ ID No. 1 of the instant invention (see attached EXHIBIT A). The reference goes on to teach polynucleotides and polypeptides and antibodies and the screening for compounds that bind to their polynucleotides and polypeptides (see abstract, p. 16, lines 19+, p. 38+, p. 49-52 and p. 61). WO 02/062975 teaches SEQ ID No. 2 which is 100% identical to SEQ ID NO. 1 of the instant invention (see attached EXHIBIT B). The reference goes on to teach screening for compounds that inhibit the activity of the polypeptide. Therefore the technical feature recited in claim 1 is not special.

Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 15 (as it reads on claim), 17 and 25 drawn to a compound that inhibits the activity of SEQ ID NO. 1 or a sequence similar to SEQ ID NO. 1.

Group II, claim(s) 2, 15 (as it reads on claim 2), 18 and 26 drawn to a compound that inhibits the expression of a gene encoding of SEQ ID NO. 1 or a sequence similar to SEQ ID NO. 1.

Group III, claim(s) 3-8, 15 (as it reads on claim 6), 16 (as it reads on claim 8) and 27 drawn to antisense and compositions comprising said antisense.

Group IV, claim(s) 9-13, 15 (as its reads on claim 11), 16 (as it reads on claim 13) and 28 drawn to antibody to SEQ ID No. 1 and compositions comprising said antibody.

Group V, claim(s) 14, 16 (as it reads on claim 14) drawn to polynucleotide encoding SEQ Id No. 1

Group VI, claim(s) 19-20 and 29 drawn to methods of screening for a compound using SEQ ID No. 1 or a sequence similar to SEQ Id NO. 1.

Group VII, claim(s) 22-23 and 30 drawn to methods of screening for a compound using a polynucleotide which encodes for a protein that is SEQ ID No. 1 or a sequence similar to SEQ Id NO. 1.

Group VIII, claim(s) 31-32 drawn to methods of treating/preventing cancer using a compound that inhibits the activity of SEQ ID No. 1 or a sequence similar to SEQ Id NO. 1.

Group IX, claim(s) 31-32 drawn to methods of treating/preventing cancer using a compound that inhibits the expression of a gene which encodes for a protein that is SEQ ID No. 1 or a sequence similar to SEQ Id NO. 1.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of WO 00/70945 and WO 02/062975, the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

Inventions of Groups I-V represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The polynucleotides of Group V and the antibody of Group IV are all structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis while the antibody is raised by immunization. Furthermore, the polynucleotide/expression cassette can be used for hybridization screening and the antibody can be used to immunopurify the antigen, for example. The compound of Groups I and II are structurally and chemically different because compound that inhibit gene expression would include primers and organic compounds, whereas those that inhibit protein activity would peptide fragments, mimetics and antibodies. The antisense of group III is different from the product of the other groups because it is composed of nucleotides and a sequence distinct from that of Group V. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Inventions VI-IX differ in the method objectives, method steps and parameters and in the reagents used. Invention VI recites a method of screening using a polypeptide whereas invention VII recites a method of screening using a polynucleotide. Similarly, inventions VIII and IX are distinct. Inventions VI-VII and VIII-IX are different because one is directed to a screening and the other is directed towards a treatment/prevention. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the

consideration of different patentability issues. Thus Inventions VI-IX are separate and distinct in having different method objectives, method steps and parameters and in the reagents used and are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Monday, Tuesday and Thursday from 7am to 1pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sheela J Huff
Primary Examiner
Art Unit 1643

sjh

EXHIBIT A

RESULT 10
AAB48958
ID AAB48958 standard; protein; 292 AA.
XX
AC AAB48958;
XX
DT 27-MAR-2001 (first entry)
XX
DE Mouse fatty acid elongation protein, SSC2.
XX
KW Mouse SSC2; murine; fatty acid elongation; very long chain fatty acid;
KW VLCFA biosynthesis; Cig30 homologue; transgenic animal; knockout animal;
KW skin development; hair growth; subcutaneous body fat; fertility;
KW thermoregulation; dermatological; ophthalmological; antiinfertility;
KW drug screening; gene therapy.
XX
OS Mus sp.
XX
PN WO200070945-A2.
XX
PD 30-NOV-2000.
XX
PF 16-MAY-2000; 2000WO-EP004371.
XX
PR 20-MAY-1999; 99US-0135084P.
XX
PA (KARO-) KAROLINSKA INNOVATIONS AB.
XX
PI Jacobsson A, Asadi A, Westerberg R, Nedergaard J, Tvrdik P;
XX
DR WPI; 2001-016322/02.
DR N-PSDB; AAC91702.
XX
PT Ssc1 (human and mouse) and Ssc2 (mouse) polynucleotides involved in fatty
PT acid elongation, useful in the treatment of diseases and disorders
PT involving skin development, hair growth, body fat mass, fertility,
PT thermoregulation and the eye.
XX
PS Claim 10; Fig 6; 135pp; English.
XX
CC The invention relates to novel murine and human proteins (AAB48956-
CC B48958) involved in fatty acid elongation, and to nucleic acids encoding
CC them (AAC91700-C91702). The proteins of the invention are murine SSC1
CC (AAB48956, encoded by AAC91700), human SSC1 (AAB48957, encoded by
CC AAC91701), and mouse SSC2 (AAB48958, encoded by AAC91702). The SSC1 and
CC SSC2 proteins are related to the mouse protein Cig30 (AAB48959), which is
CC itself related to the yeast proteins ELO1 (J0343, AAB48962), ELO2 (FEN1,
CC AAB48961) and ELO3 (SUR4, AAB48960). Moreover, SSC1 and SSC2 are able to
CC complement ELO1, ELO2 and/or ELO3 mutations in yeast. The invention also
CC relates to expression vectors, host cells and non-human transgenic
CC animals comprising an Ssc1 or Ssc2 nucleic acid; the recombinant
CC production of SSC1 or SSC2; an antibody which binds to SSC1 or SSC2; an
CC Ssc1, Ssc2 or Cig 30 knockout non-human animal; and methods of
CC identifying modulators of SSC1 or SSC2 activity, agents which affect
CC fatty acid elongation, agents which bind to SSC1 or SSC2, and drug
CC candidates which may be useful in the treatment of skin, hair or eye
CC disorders. SSC1, SSC2, their variants or fragments, and transgenic
CC animals of the invention are useful for identifying substances which
CC modulate fatty acid elongation or SSC1 or SSC2 activity or function, or
CC which have a therapeutic effect on a disorder of the mammalian skin, hair
CC or eyes. SSC1 and SSC2 proteins, nucleic acids and modulators are useful
CC for treating diseases and disorders involving skin development, hair
CC growth, subcutaneous body fat mass, fertility, thermoregulation, and/or
CC the eye. The nucleic acids are also useful in gene therapy of disorders
CC or defects of very long chain fatty acid (VLCFA) biosynthesis. The
CC present sequence represents mouse SSC2
XX
SQ Sequence 292 AA;

Query Match 89.8%; Score 1433; DB 4; Length 292;
Best Local Similarity 88.5%; Pred. No. 6.6e-153;
Matches 262; Conservative 16; Mismatches 14; Indels 4; Gaps 1;

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Qy          1 MEHLKAFDDEINAFLDNMFGPRDSRVRGWFTLDSYLPTFFLTVMYLLSIWLGNKYMKNRP 60
              || |||||:|:||||||||||||||||||| |||||||| ||: ||||||||||||||||
Db          1 MEQLKAFDNEVNAFLDNMFGPRDSRVRGWFLLDSYLPTFILTITYLLSIWLGNKYMKNRP 60
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Qy          61 ALSLRGILTLYNLGITLLSAYMLAELILSTWEGGYNLQCQDLTSAGEADIRVAKVLWWYY 120
               ||||||||||||| ||||||||| |||||:||||||||||:| |||| |:||||||||||
Db          61 ALSLRGILTLYNLAITLLSAYMLVELILSSWEGGYNLQCQNLDSAGEGDVRVAKVLWWYY 120

Qy         121 FSKSVEFLDTIFFVLRKKTSQITFLHVYHHASMFNIWWCVLNWIPCGQSFFGPTLNSFVH 180
               ||| ||||||||||||||||||||||||||||||||||||||||||||||||||||||:|
Db         121 FSKLVEFLDTIFFVLRKKTSQITFLHVYHHASMFNIWWCVLNWIPCGQSFFGPTLNSFIH 180

Qy         181 ILMYSYYGLSVFPSMHKYLWWKKYLTQAQLVQFVLTITHTMSAVVKPCGFPFGCLIFQSS 240
               ||||||||||||||||||||||||||||||||||||||:||||||||||||||||||||
Db         181 ILMYSYYGLSVFPSMHKYLWWKKYLTQAQLVQFVLTITHTLSAVVKPCGFPFGCLIFQSS 240

Qy         241 YMLTLVILFLNFYVQTYRKKPMKKDMQEPPAGKEVKNGFSKAYFTAANGVMNKKAQ 296
               ||:||||||||||:||||||||:||::||    ||||||| ||:   |||: :|||||
Db         241 YMMTLVILFLNFYIQTYRKKPVKKELQE----KEVKNGFPKAHLIVANGMTDKKAQ 292
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EXHIBIT B

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RESULT 1
ABB81999
ID   ABB81999 standard; protein; 296 AA.
XX
AC   ABB81999;
XX
DT   05-DEC-2002  (first entry)
XX
DE   Protein identified by trembl/AK000348/AK00034-1.
XX
KW   Human; elongase HSELO1-like protein; antidiabetic; cytostatic; elongase;
KW   anti-Parkinsonian; cerebroprotective; neuroprotective; nootropic;
KW   enzyme therapy.
XX
OS   Homo sapiens.
XX
PN   WO200262975-A2.
XX
PD   15-AUG-2002.
XX
PF   07-FEB-2002; 2002WO-EP001263.
XX
PR   08-FEB-2001; 2001US-0267150P.
PR   16-NOV-2001; 2001US-0331450P.
PR   06-DEC-2001; 2001US-0336164P.
XX
PA   (FARB ) BAYER AG.
XX
PI   Zhu Z;
XX
DR   WPI; 2002-627545/67.
XX
PT   New human elongase HSELO1-like protein useful for treating diabetes,
PT   cancer,, and central nervous system disorders. e.g. cerebrovascular
PT   disease, Parkinson's disease, stroke dementia, multiple sclerosis, or
PT   dementias.
XX
PS   Disclosure; Fig 3; 170pp; English.
XX
CC   The invention relates to human elongase HSELO1-like protein and encoding
CC   polynucleotide. The protein can be expressed by standard recombinant
CC   methodology. The human elongase HSELO1-like protein is useful in raising
CC   specific antibodies that can block the enzyme and effectively reduce its
CC   activity, and for treating diabetes, cancer, and central nervous system
CC   disorders (e.g. cerebrovascular disease, Parkinson's disease, stroke
CC   dementia, multiple sclerosis, dementias such as Alzheimer's disease, or
CC   Huntington's disease). HSELO1-like proteins may also be used in
CC   diagnostic assays for detecting diseases and abnormalities or
CC   susceptibility to diseases and abnormalities related to the presence of
CC   mutations in the nucleic acid sequences that encode the enzyme. The
CC   expression vector or the reagent is useful in the preparation of a
CC   medicament for modulating the activity of an elongase HSELO1-like protein
CC   in a disease including cancer, diabetes, CNS disorder, metabolic disease,
CC   asthma, or chronic obstructive pulmonary disorder. The present sequence
CC   represents a protein identified by trembl/AK000348/AK00034-1
XX
SQ   Sequence 296 AA;

  Query Match             100.0%;  Score 1596;  DB 5;  Length 296;
  Best Local Similarity   100.0%;  Pred. No. 2.5e-171;
  Matches  296;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MEHLKAFDDEINAFLDNMFGPRDSRVRGWFTLDSYLPTFFLTVMYLLSIWLGNKYMKNRP 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MEHLKAFDDEINAFLDNMFGPRDSRVRGWFTLDSYLPTFFLTVMYLLSIWLGNKYMKNRP 60

Qy         61 ALSLRGILTLYNLGITLLSAYMLAELILSTWEGGYNLQCQDLTSAGEADIRVAKVLWWYY 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 ALSLRGILTLYNLGITLLSAYMLAELILSTWEGGYNLQCQDLTSAGEADIRVAKVLWWYY 120

Qy        121 FSKSVEFLDTIFFVLRKKTSQITFLHVYHHASMFNIWWCVLNWIPCGQSFFGPTLNSFVH 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 FSKSVEFLDTIFFVLRKKTSQITFLHVYHHASMFNIWWCVLNWIPCGQSFFGPTLNSFVH 180

Qy        181 ILMYSYYGLSVFPSMHKYLWWKKYLTQAQLVQFVLTITHTMSAVVKPCGFPFGCLIFQSS 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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Db        181 ILMYSYYGLSVFPSMHKYLWWKKYLTQAQLVQFVLTITHTMSAVVKPCGFPFGCLIFQSS 240

Qy        241 YMLTLVILFLNFYVQTYRKKPMKKDMQEPPAGKEVKNGFSKAYFTAANGVMNKKAQ 296
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 YMLTLVILFLNFYVQTYRKKPMKKDMQEPPAGKEVKNGFSKAYFTAANGVMNKKAQ 296
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